

APPLICATION

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IN

**THE UNITED STATES
PATENT AND TRADEMARK OFFICE**

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for

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BIOROOT ENDOSSEOUS IMPLANT

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BIOROOT ENDOSSEOUS IMPLANT

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1. FIELD OF INVENTION

The present invention relates generally to the field of implant dentistry, and more
10 particularly to the design of one- and two-stage endosseous implants.

2. BACKGROUND OF THE INVENTION

Endosseous, i.e., intra boney, implants are commonly used to support fixed or
15 removable prostheses where a patient's natural roots have been lost, and as a consequence,
support is lacking to provide an adequate foundation onto which the dentist can rebuild a
dentition. As the aging population retains more of their natural teeth, and as the younger
generations want to take advantage of more conservative approaches offered by implant
dentistry, e.g., using a single implant rather than cutting down adjacent teeth to support a
20 short span bridge to replace a missing tooth, implant dentistry has gained more and more
popularity and has moved into the mainstream of dentists worldwide.

The current implant design is based on an endosseous fixture, a titanium screw that
acts as an artificial root. Bränemark, *Tissue-Integrated Prostheses* (1985). Modifications
made to the endosseous fixture have centered on the macro structure of the implant (e.g., by
25 exchanging the screw with a press-fit/cylindrical implant, a stepped screw or cylinder, or a
tapered screw or cylinder), (Brunski J.B., *Biomechanics Of Oral Implant*, Future Research
Directions NIH Consensus Development Conference on Dental Implants, 1988; Kirsch A. et
al., *The IMZ Osseointegrated Implant System*, Dent. Clin. North Am. 1989 (4), 33:733-791;
Niznick G.A., *A Multimodal Approach To Implant Prosthodontics*, Dent. Clin. North Am.
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Commercially Available Oral Implant Systems*, Id. 1993:8:622-633; Siegela D. et al.,
*Numerical Investigations Of The Influence Of Implant Shape On Stress Distribution In The
Jaw Bone*, Id. 1989:4:333-340; Olsson M. et al., *MkII-a Modified Self-Tapping Bränemark
Implant: 3-Year Results*, Id. at 1995:10:15-21; Langer B. et al., *The Wide Fixture: A
35 Solution For Special Bone Situations And A Rescue For The Compromised Implant, Part 1*,
Id., 1993:8:400-408; Schnitman P.A. et al., *Implants For Partial Edentulism*, NIH

- Consensus Development Conference On Dental Implants, 1988), on the micro structure (e.g., surface modifications such as use of machined titanium, blasted titanium, titanium alloy, acid-etched titanium, plasma-sprayed titanium and hydroxyappatite coating such as growth factors and proteins), (Baier R.E. *et al.*, *Future Directions In Surface Preparation Of Dental Implants*, NIH Consensus Development Conference On Dental Implants, 1988; Young F.A., *Future Directions In Dental Implant Materials Research*, *Id.*; Krauser J., *Hydroxylappatite-Coated Dental Implants*, Dent. Clin. North Am. 1989, 33:4:879-903; Buser D. *et al.*, *Tissue Integration Of One-Stage ITI Implants: 3-Year Results Of A Longitudinal Study With Hollow-Cylinder And Hollow-Screw Implants*, Int. J. Oral Maxillofac. Implants, 1991:6:405-412), on one-vs-two-stage designs, (Weber H.P. *et al.*, *Comparison Of Healed Tissues Adjacent To Submerged And Non-Submerged Unloaded Titanium Dental Implants*, Clin. Oral Impl. Res. 1996:7:11-19; Busser D. *et al.*, *Tissue Integration Of One-Stage ITI Implants: 3-Year Results Of A Longitudinal Study With Hollow-Cylinder and Hollow-Screw Implants*, Int. J. Oral Maxillofac Implants 1991:6:405-412), and on modifying the connection between the implant and its abutment (e.g., either internal hex, external hex, standard hex, tall hex, wide hex, etc.), (U.S. Pat. No. 4,960,381; U.S. Pat. No. 5,407,359; U.S. Pat. No. 5,209,666; U.S. Pat. No. 5,110,292).

Irrespective of the design variables discussed above, current systems have two general characteristics in common: First, the abutment-implant interface is planar; and second, the area intended for bone apposition, *i.e.*, osseointegration, terminates parallel to the abutment-implant interface, 360 degrees around the implant.

Traditionally, endosseous implants were designed for treatment of the fully edentulous patient. In general, this particular patient population exhibits reduced bone-tissue volume, both in height and width when compared to the partially edentulous patient with recent or impending tooth loss. However, the bone-tissue morphology of partially edentulous patients significantly differs from that of fully edentulous patients, in that the naturally occurring supporting bone structures reveal a scalloped architecture around the tooth.

Currently available implant technology does not take the different bone-tissue morphologies into consideration. Heretofore use of an implant with an intended bone-tissue apposition surface parallel to a flat abutment-implant interface has led to either (1) placement of soft-tissue intended parts of the implant within bone-tissue, leading to bone-tissue resorption in these areas, and/or (2) exposure of hard-tissue intended surfaces to the soft tissue, resulting in possible peri-implant infections due to bacterial colonization around the rough surface and potential loss of the implant.

3. SUMMARY OF THE INVENTION

The present invention is directed towards novel endosseous implants, which are structured to better maintain hard and soft-tissue in the area where the implant exits from the bone-tissue and transverses the soft-tissue. More particularly, the implants of the

5 present invention are designed so that areas intended for hard- and soft-tissue apposition exhibit a scalloped appearance, including convex and/or concave patterns, which approximate the naturally occurring bone morphology. Thus, the implants of the present invention provide substantially increased attachment possibilities for both bone-tissue and soft-tissue, thereby facilitating bone-tissue and soft-tissue preservation and maintenance.

10 The present invention will enable the surgeon to place an implant into residual bone with the surface of the implant intended for bone-tissue contact and apposition (machined or roughened, surface coated or textured, altered with biologic modifiers such as proteins and growth factors, or any combination thereof) being substantially in contact with bone-tissue, and with the surface intended for soft-tissue apposition (polished/treated with soft tissue 15 specific surface modifications) being substantially in contact with soft-tissue.

More specifically, the implant, according to an embodiment of the present invention, is a substantially cylindrical shaft made from a biocompatible material having a distal end and a proximal end. A bone-tissue/soft-tissue transition region and a abutment-implant interface are both disposed towards the proximal end of the shaft. The bone-tissue/soft-
20 tissue transition region is defined as the approximate region of the shaft and/or the abutment-implant interface where the implant exits the bone-tissue and transverses into the soft-tissue. The bone-tissue/soft-tissue transition region has a bone-tissue apposition surface configured to approximate the physiological contours of the alveolar bone. In a two-stage implant, the abutment-implant interface may be either substantially planar, 25 approximately 90° to the longitudinal axis of the shaft, or contoured to approximate the contour of the alveolar bone. In a one-stage implant the abutment is permanently attached to the abutment-implant interface, or an integral part of the implant itself. The abutment, in both one-and two-stage implants, has an abutment-crown interface, which is either substantially planar or contoured to approximate the contour of the alveolar bone, and a
30 chimney onto which the crown is secured.

An implant constructed according to the principles of the present invention facilitates hard- and soft-tissue maintenance, increases longevity of the implant and improves its aesthetic appearance. As will be readily apparent to the skilled artisan, the present invention may be applied to numerous prosthetic applications, such as, but not 35 limited to, a single tooth replacement, an abutment for a bridge (fixed partial denture)

regardless of the nature of the other abutment (natural tooth or implant), a pier abutment or an over denture abutment.

4. BRIEF DESCRIPTION OF THE DRAWINGS

- 5 FIG. 1 depicts a frontal view of a prior art implant;
FIG. 2 depicts an interproximal view of the prior art implant in FIG. 1;
FIG. 3 depicts a frontal view an implant according to an embodiment of the present invention;
FIG. 4 depicts an interproximal view of the implant in FIG. 3;
10 FIG. 5A depicts a three-dimensional top frontal view of the implant in FIG. 3;
FIG. 5B depicts a three-dimensional interproximal top view of the implant in FIG. 3
FIG. 6 depicts a frontal view of an implant according to another embodiment of the present invention;
FIG. 7 depicts an interproximal view of the implant in FIG. 6;
15 FIG. 8 depicts a three-dimensional top view of the implant in FIG. 6;
FIG. 9 shows a frontal view of an implant according to another embodiment of the present invention;
FIG. 10 depicts an interproximal view of the implant in FIG. 9;
FIG. 11 depicts a frontal view of an implant according to another embodiment of the
20 present invention; and
FIG. 12 depicts an interproximal view of the implant in FIG. 11.

5. DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

- FIGS. 1 and 2 show prior art implant 10, abutment-implant interface 12, abutment
25 14 and crown 16 constructed according to the current state of the art. Implant 10, according to the current state of the art, has a bone apposition surface 17, typically threads or otherwise roughened surface, extending into alveolar bone 18. Abutment-implant interface 12 extends partially into the alveolar bone and has polished surface 20, which is not suitable for bone apposition. Use of implant 10, constructed according to the current state of the art,
30 results in bone-tissue resorption in bone-tissue/soft-tissue transition region 22 because polished surface 20 contacts bone-tissue, which as discussed, leads to bone resorption. Any loss of natural bone structure or topography is highly undesirable from both structural and aesthetic perspectives. Even the smallest bone-tissue loss between the tooth and an implant will lead to soft-tissue shrinkage due to lack of boney support, resulting in "black triangles"
35 (open spaces) between the teeth—a highly unaesthetic situation.

FIGS. 3 and 4 show a two-stage implant according to an embodiment of the present invention. Implant 24 has shaft 26, substantially planar abutment-implant interface 28, distal end 30, proximal end 32 and bone-tissue/soft-tissue transition region 34. Abutment 36 and crown 38 are attached to implant 24 using means well known to the skilled artisan for two-stage implants. Implant 24 is made from a biocompatible material, including but not limited to, metal, ceramic, glasses or any combination thereof. Preferably implant 24 is made from titanium or an alloy thereof.

Bone-tissue/soft-tissue transition region 34 has a scalloped bone-tissue apposition surface 42, which approximately follows the naturally occurring contours of existing bone 40, and a scalloped soft-tissue apposition surface 44, which approximately follows the naturally occurring contours of the existing soft-tissue (not shown). Thus, there are two distinctive scalloped tissue-attachment surfaces: bone-tissue apposition surface 42 to maintain the naturally occurring bone-tissue morphology; and soft-tissue apposition surface 44 to maintain the naturally occurring soft-tissue morphology. The degree of scalloping or the height of the convex and concave regions depends on, *inter alia*, the degree of existing bone-tissue resorption, the size of the implant, the implant location within the arch, the bone morphology and the soft-tissue morphology. The dimensions are similar to the scalloped appearance of the cemento-enamel (CE) junction observed on natural teeth. The vertical difference between the highest and lowest point of the scalloped margin ranges from less than 1mm on posterior teeth to approximately 3-5mm on anterior teeth. By way of example, bone-tissue apposition surface 42 can be obtained by machining, application of textured surfaces, acid etching, blasting with particles, applying growth factor, applying protein, or other materials that promote, enhance, and/or maintain bone-tissue growth and/or apposition. Also by way of example, soft-tissue apposition surface 44 can be achieved by polishing or other treatment that leaves a surface to promote, enhance, and/or maintain soft-tissue growth and/or apposition. Below the bone-tissue/soft-tissue transition region 34, shaft 26 has threads 45, or other means well known in the art, to anchor the implant into the alveolar bone.

In use, the surgeon inserts distal end 30 into the alveolar bone such that bone-tissue apposition surface 42 and soft-tissue apposition surface 44 approximately mirror the existing bone- and soft-tissue morphology respectively. The implant should be aligned such that the highest points of bone apposition surface 42 are substantially aligned with the interproximal areas of the bone-tissue and such that the lowest points are substantially aligned with the buccal and lingual area of the bone-tissue. In a two-stage process, the surgeon sutures tissue over the implant, waits several months for the bone to adhere to the

implant, opens the tissue, attaches abutment 36 to abutment-implant interface 28 and attaches crown 38 to abutment 36. Bone-tissue apposition surface 42 and soft-tissue apposition surface 44 maintain bone- and soft-tissue attachment levels and facilitate prevention of peri-implant infections, which occur due to increased peri-implant pocket
5 depths frequently observed with the prior art implant designs. Therefore, implants constructed according to the present invention increase the longevity of the implant and improve the aesthetic appearance of the restoration.

Referring to FIGS. 5A and 5B, abutment-implant interface 28 has substantially planar upper surface 25, which is approximately 90° to the longitudinal axis of shaft 26, and
10 connecting means 46 for connecting abutment 36 (FIGS. 3 and 4) to abutment-implant interface 28. Connecting means 46 is well known in the art and includes, but is not limited to, internal hex, external hex, standard hex, tall hex, wide hex or camlog. In an alternative embodiment of the present invention, as shown in FIGS. 6-8, abutment-implant interface 48 has at least its edges contoured to approximate the contours of the alveolar bone, thereby
15 defining a contoured upper surface 50 (FIG. 8) surrounding connecting means 46. Also provided in this alternative embodiment is abutment 52, which has lower contoured surface 54 configured to substantially mate with contoured upper surface 50. The upper and lower contoured surfaces provide additional lateral support between abutment 52 and abutment-implant interface 48. Additionally, contoured upper surface 48 of this alternative
20 embodiment results in a narrower depth between gum line 54 and abutment-implant interface 48 (FIGS. 6 and 7), thus enhancing longevity of the restoration as a result of decreased pocket depths.

A skilled artisan will readily recognize that the principles of the present invention can be equally applied to one-stage as well as two-stage processes. For example, FIGS. 9
25 and 10 show one-stage implant 58, according to another embodiment of the present invention. Implant 58 includes shaft 60, distal end 62, proximal end 64 and bone-tissue/soft-tissue transition region 66 with scalloped bone-tissue apposition surface 42 and scalloped soft-tissue apposition surface 44, as substantially described above. Abutment 69 is permanently attached to the one-stage implant 58 as is well known in the art.

30 One-or two-stage implants, according to alternative embodiments of the present invention, may include either a planar abutment-crown interface 68 (FIGS. 3, 4, 9 and 10) or a contoured abutment-crown interface 70 (FIGS. 6, 7, 11 and 12), the latter of which substantially matches the natural contour of the alveolar bone. Contoured abutment-crown interface 70 allows for crown 38, in both one-and two-stage implants, to extend further
35 towards the gum line, thereby resulting in a more aesthetically pleasing restoration.

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Chimney 72, or other means well known to the skilled artisan, is provided in both one-and two-stage implants according to the present invention for attaching crown 38 to the abutment.

Although various embodiments of the present invention have been described, the
5 descriptions are intended to be merely illustrative. Thus, it will be apparent to the skilled artisan that modifications may be made to the embodiments as described herein without departing from the scope of the claims set forth below.

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